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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,372	07/02/2001	Mark E. Van Dyke	KER020/4-005CON	3035

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/899,372	VAN DYKE ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-65 and 67-96* is/are pending in the application.

4a) Of the above claim(s) *69-92 and 94-96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-65,67,68 and 93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/16/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for reconsideration filed 12/14/2006; and IDS both filed 10/16/2006.

Claims 55-65, 67-93 are pending.

Claims 69-92, 94-96 are withdrawn as being directed to a nonelected invention. Election was made without traverse in Paper filed 02/28/2002.

Claims 55-65, 67, 68 and 93 are included in the prosecution.

The rejection of claim 93 as lacking enablement for topical composition has been overcome by virtue of applicants' remarks.

The following rejections have been discussed in the previous office action, and are maintained for reasons of record:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 55-56, 67, and 68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for topical composition comprising water soluble peptides, does not reasonably provide enablement for compositions other than topical, i.e. oral or parentral. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is composition comprising soluble peptides having a specific molecular weight.

The breadth of the claims: The claims are broad. The claims encompass all the possible formulations of compositions including parentral.

The state of the prior art: The state of the art recognized peptides administered topically to treat wounds, US 5,932,552.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The specification provides no guidance, in the way written description, on composition comprising water soluble peptides that is administered by any route other than topical administration for wound treatment or as cell scaffold. It is not obvious from the disclosure of topical composition comprising peptides if any other composition comprising peptide will work in terms of wound treatment. On page 5, lines 10-17, applicants disclose that peptide is placed over the wound as powder, or formulated into cream, gel, or cast the peptide powder onto polymer or keratin dressing. On page 9, lines 8-19, applicants disclose the peptide used for growth of keratinous tissue, treating external wound, or treating aging skin, and all are achieved by admixing the peptide with a cream, lotion, or gel. Therefore, applicants' disclosure supports topically acting formulation, and does not support any other formulation that may act systemically. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the formulations fall within the scope of a claim will possess the alleged activity. *See In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of guidance from the specification and from the prior art with regard to composition comprising soluble peptides used for treating wound or tissue scaffold that is administered by any other route than topically makes practicing the claimed invention unpredictable in the terms of other forms of the composition.

The presence or absence of working examples: The specification discloses topical composition for treating wounds. No working examples to show other compositions such as parentral that acts topically. Therefore, the specification has enabled only topical compositions.

The quantity of experimentation necessary: The practitioner would turn to trial and error experimentation to practice the instant composition for treating wound or for implantation using non-topical composition without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

Response to Arguments

3. Applicant's arguments filed 12/14/2006 have been fully considered but they are not persuasive. Applicants argue that the issue is not whether specification enables all the compositions to which the peptide composition can be added, but rather, the enablement of the peptide composition is independent of adding it to a particular type of carrier. The specification has adequate description of how to obtain the peptide composition and how to use it to stimulate growth of useful cell types. Applicants argue that on page 10 the composition is disclosed to be given orally as a supplement. No undue experimentation is necessary to use the present composition orally.

In response to these arguments, the examiner position is that the specification has enabled how to make the peptide composition and how to use it topically to stimulate growth of useful cell types, and has not enabled any uses other than topically for stimulating wound healing and cell growth. On page 5, lines 10-17, applicants

disclose that peptide is placed over the wound as powder, or formulated into cream, gel, or cast the peptide powder onto polymer or keratin dressing. On page 9, lines 8-19, applicants disclose the peptide used for growth of keratinous tissue, treating external wound, or treating aging skin, and all are achieved by admixing the peptide with a cream, lotion, or gel. On page 10, lines 3-5 applicants stated that: "In another use of the invention, the peptide can be applied internally to damaged keratinous tissue lining the GI tract by orally administering the peptide". Hence, applicants disclosed the peptide composition administered orally to act topically on damaged GIT mucosa, and not systemically, even when administered orally. The composition is intended to be applied to the damaged keratinous tissues either skin or mucosa of GIT, and not intended to be administered systemically as encompassed by the scope of the claims. Therefore, the specification has only enabled how to make and how to use topical composition comprising soluble peptides applied to the keratinous tissues.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 55-65, 67, 68 and 93 rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,276,138 ('138).

US '138 teaches a solubilized keratin powder from animal hair or wool (abstract; col.65-67). The method of production included the steps of oxidation by hydrogen peroxide or peracetic acid; filtration, neutralization, precipitation of a powder; and washing the filtrate with solvent such as acetone, methanol or ethanol (col.3, lines 3-5, 21-24; col.4, lines 3, 20-28; col.5 and 6, example 1). The powder is used in cosmetics (col.4, lines 22-23).

However, US '138 does not teach the low molecular weight of the peptide or its amount in the composition.

The claimed molecular weights do not impart patentability to the claims, absent evidence to the contrary.

The amount of the peptides does not impart patentability to composition claims since it has been held that where the general conditions of a claim are disclosed in the

prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide solubilized peptides disclosed by US '138, and select the concentration and acidity of the oxidizing agent and time for hydrolysis of the keratinous material to obtain peptide of desired molecular weight suitable for the intended use.

Response to Arguments

7. Applicant's arguments filed 12/14/2006 have been fully considered but they are not persuasive. Applicants argue that US '138 does not describe any isolated fraction of keratin peptides that is produced by precipitation from aqueous solution with a water-miscible organic solvent, nor does it contain any description of the small peptides that are the subject of the present claims. Applicants argue that US '138 does not teach the claimed molecular weights of the peptides and same step of precipitation. Applicants argue that no prima facie case of obviousness has been established.

In response to these arguments, the examiner position is the claims are directed to composition comprising soluble peptide, and the elements of the composition are disclosed by US '138. The peptide disclosed by US '138 used for cosmetics as desired by applicants. Therefore, the product of the prior art is capable functioning the same way as the present invention. At col. 4, lines 18-22, US '138 teaches powder prepared by treating the gelled precipitate with a polar solvent such as alcohol, acetone, i.e. the

peptide is precipitated from aqueous solution with organic solvent as required by the present claims. In addition, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The difference between the peptide of present claims and the peptide of the prior art is the molecular weight. US '183 at col.5, lines 22-25 teaches that low molecular weight peptides are also produced. According to the intended use, one having ordinary skill in the art would have selected the desired fraction of peptide with the desired molecular weight and also one having ordinary skill in the art would determine the amount of that fraction. For skin application and cosmetics, the skilled artisan would select low molecular weight peptides as evidenced by the disclosure of US 5,314,873 (873) that amino acids of low molecular weight of $\leq$1,000 are capable for imparting proliferation activity to dermal cells of human, see the abstract.

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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IG

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